## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

J. Jan

Applicant:

YOUSEF et al.

Examiner:

Unknown

11757.0080USWO

jal No.:

10/526,029

5441

Group Art Unit:

1632

Confirmation

September 20, 2005

Docket:

1032

No.:

Notice of Allow.

N/A

Date:

Title:

METHODS FOR DETECTING BREAST AND OVARIAN CANCER

### **CERTIFICATE UNDER 37 CFR 1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on September 14, 2006.

Name: Sarah Dannecker

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

23552
PATENT TRADEMARK OFFICE

Sir:

We are transmitting herewith the attached:

☐ Transmittal Sheet in duplicate containing Certificate of Mailing

Supplemental Information Disclosure Statement, Form 1449, 36 Reference(s)

Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903 612.332.5300

Name: Mark T. Skoog

Reg. No.: 40,178

MTS/sbd



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

YOUSEF et al.

Examiner:

Unknown

Serial No.:

10/526,029

Group Art Unit:

1632

Filed:

September 20, 2005

Docket No.:

11757.0080USWO

Title:

METHODS FOR DETECTING BREAST AND OVARIAN CANCER

#### **CERTIFICATE UNDER 37 CFR 1.8:**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 September 14, 2006.

Name: Sarah Dannecker

# **INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

### Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked

as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903

Minneapolis, Minnesota 55402-0903

(612) 332-5300

Dated: September 14, 2006

Reg. No. 40,178

MTS/sbd

FORM 1449*	FORMATION DISCLOSURE STATEMENT	Docket Number: Application Number: 11757.0080USWO 10/526,029  Applicant: YOUSEF et al.  Filing Date: September 20, Group Art Unit: 1632	
ン	IN AN APPLICATION	Applicant: YOUSEF et al.	
SEP 1 8 2006 8	(Use several sheets if necessary)	Filing Date: September 20, 2005	Group Art Unit: 1632

		U	S. PATENT DOCUMEN	ITS			
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS		G DATE OPRIATE
-							
	DOGULATIVE 10		EIGN PATENT DOCUM				
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS		LATION
···-						YES	NO
		<del>-   </del>					
	ОТНЕ	R DOCUMENTS	(Including Author, Title,	Date, Pertinent l	Pages, Etc.)		76
		ession of a Huma	Journal of Biological Che n Stratum Corneum Tryps				
		Christopoulos et al., 1992, Analytical Chemistry 64: 342-346, "Enzymatically Amplified Time-Resolved Flurescence Immunoassay with Terbium Chelates".  Dhar et al., 2001, Clinical Cancer Research 7: 3393-3398, "Analysis of Normal Epithelial Cell Specific-1 (NES1)/Kallikrein 10 mRNA Expression by in Situ Hybridixation, a Novel Marker for Breast Cancer".				ved	
	Diamano Ovarian	Diamandis et al., 2002, Cancer Research 62: 295-300, "Human Kallikrein 11: A New Biomarker of Prostate ar Ovarian Carcinoma".					rostate and
	Diamano of novel	Diamandis et al., 2001, Expert Rev. Mol. Diagn. 1: 182-190, "Human tissue kallikrein gene family: a rich source of novel disease biomarkers".  Diamandis et al., 2000, Clinical Chemistry 46: 1855-1858, "New Nomenclature for the Human Tissue Kallikrein Gene Family".					
			inical Biochemistry 33: 579 Ovarian Carcinoma".	9-583, "Human l	Kallikrein 6 (Zyme/	/Protease M/N	Neurosin): A
	Diamand (Zyme/P	lis et al., 2000, <i>Cli</i> rotease M/Neuros	inical Biochemistry 33: 36! in) and Preliminary Clinical	9-375, "Immuno al Applications"	fluorometric Assay	of Human K	allikrein 6
		al., 2001, <i>Clinical</i> Ovarian Carcinoma	Cancer Research 7: 2363-	-2371, "Human l	Kallikrein 4 (KLK4	) Is Highly Ex	pressed in
	Goyal et Supresso		Research 58: 4782-4786,	"The Role for N	ES1 Serine Proteas	e as a Novel	Гитог

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

FORM 1449* INFORMATION DISCLOSURE STATEMENT	Docket Number: Application Number: 11757.0080USWO 10/526,029		
IN AN APPLICATION	Applicant: YOUSEF et al.		
(Use several sheets if necessary)	Filing Date: September 20, 2005	Group Art Unit: 1632	

**	Kim et al., 2001, <i>British Journal of Cancer</i> 84: 843-650, "Human kallikrein gene 5 (KLK5) expression is an indicator of poor prognosis in ovarian cancer".
	Lilja et al., 1991, Clinical Chemistry 37: 1618-1625, "Prostate-Specific Antigen in Serum Occurs Predominantly in Complex with $\alpha_1$ -Antichymotrypsin".
	Liu et al., 1996, Cancer Research 56: 3371-3379, "Identification of a Novel Serine Protease-like Gene, the Expression of Which is Down-Regulated during Breast Cancer Progression".
	Luo et al., 2002, <i>British Journal of Cancer</i> 86: 1790-1796, "Higher expression of human kallikrein 10 in breast cancer tissue predicts tamoxifen resistance".
	Luo et al., 2001, <i>Clinical Chemistry</i> 47: 237-246, "Immunofluorometric Assay of Human Kallikrein 10 and Its Identification in Biological Fluids and Tissues".
	Luo et al., 2001, Clinical Cancer Research 7: 2372-2379, "Prognostic Value of Human Kallikrein 10 Expression in Epithelial Ovarian Carcinoma".
	Petraki et al., 2002, <i>The Journal of Histochemistry &amp; Cytochemistry</i> 50: 1247-1261, "Human Kallikrein 10 Expression in Normal Tissues by Immunohistochemistry".
	Petraki et al., 2001, <i>The Journal of Histochemistry &amp; Cytochemistry</i> 49: 1431-1441, "The Spectrum of Human Kallikrein 6 (Zyme/Protease M/Neurosin) Expression in Human Tissues as Assessed by Immunohistochemistry"
	Rittenhouse et al., 1998, Critical Reviews in Clinical Laboratory Sciences 35: 275-368, "Human Kallikrein 2 (hK2) and Prostate-Specific Antigen (PSA): Two Closely Related, but Distinct, Kallikreins in the Prostate".
	Saedi et al., 2001, <i>Int. J. Cancer</i> 94: 558-563, "Human Kallikrein 2 (HK2), but Not Prostate-Specific Antigen (PSA), Rapidly Complexes with Protease Inhibitor 6 (PI-6) Released From Prostate Carcinoma Cells".
	Schmalfeldt et al., 2001, Clinical Cancer Research 7: 2396-2404, "Increased Expression of Matrix Metalloproteinases (MMP)-2, MMP-9, and the Urokinase-Type Plasminogen Activator Is Associated with Progression From Benign to Advanced Ovarian Cancer".
	Shevchenko et al., 1997, <i>Journal of Protein Chemistry</i> 16: 481-490, "Peptide Sequencing by Mass Spectrometry for Homology Searches and Cloning of Genes".
	Stenman et al., 1991, Cancer Research 51: 222-226, "A Complex Between Prostate-specific Antigen and $\alpha_1$ -Antichymotrypsin is the Major Form of Prostate-specific Antigen in Serum of Patients with Prostatic Cancer: Assay of the Complex Improves Clinical Sensitivity for Cancer".
	Stephan et al., 2000, Cancer Epidemiology, Biomarkers & Prevention 9: 1133-1147, "Molecular Forms of Prostate-specific Antigen and Human Kallikrein 2 as Promising Tools for Early Diagnosis of Prostate Cancer".
	Tanimoto et al., 1999, Cancer 86: 2074-2082, "The Stratum Corneum Chymotryptic Enzyme That Mediates Shedding and Desquamation of Skin Cells Is Highly Overexpressed in Ovarian Tumor Cells".
	Underwood et al., 1999, Cancer Research 59: 4435-4439, "Cloning of Tumor-associated Differentially Expresse Gene 14, a Novel Serine Protease Overexpressed by Ovarian Carcinoma".
	Yousef et al., 2003, <i>Current Genomics</i> 4: 147-165, "Human Kallikreins: Common Structural Features, Sequence Analysis and Evolution".

EXAMINER	DATE CONSIDERED
270 (17) (2)	DATE CONSIDERED
· · · · · · · · · · · · · · · · · · ·	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

FORM 1449* INFORMATION DISCLOSURE STATEMENT	Docket Number: 11757.0080USWO	Application Number: 10/526,029
IN AN APPLICATION	Applicant: YOUSEF et al.	
(Use several sheets if necessary)	Filing Date: September 20, 2005	Group Art Unit: 1632

Yousef et al., 2002, <i>Tumor Biol.</i> 23: 185-192, "Expanded Human Tissue Kallikrein Family-A Novel Panel of Cancer Biomarkers".
Yousef et al., 2002, Minerva Endocrinol. 27: 157-166, "Kallikreins, steroid hormones and ovarian cancer: is there a link?"
Yousef et al., 2002, <i>Urology</i> 60: 714-718, "Differential Expression of Kallikrein Gene 5 In Cancerous and Normal Testicular Tissues".
Yousef et al., 20002, Clinical Chemistry 48: 1241-1250, "Human Kallikrein Gene 5 (KLK5) Expression by Quantitative PCR: An Independent Indicator of Poor Prognosis in Breast Cancer".
Yousef et al., 2002, Biol. Chem. 383: 1045-1057, "Human Tissue Kallikreins: A New Enzymatic Cascade Pathway".
Yousef et al., 2000, Biochemical and Biophysical Research Communications 276: 125-133, "Genomic Organization of the Human Kallikrein Gene Family on Chromosome 19q13.3-q13.4".
Yousef et al., 2001, Endocrine Reviews 22: 184-204, "The New Human Tissue Kallikrein Gene Family: Structure, Function, and Association to Disease".
Yousef et al., 1999, <i>The Journal of Biological Chemistry</i> 274: 37511-37516, "The New Kallikrein-like Gene, KLK-L2".
Yu et al., 1993, <i>Clinical Chemistry</i> 39: 2108-2114, "Ultrasensitive Time-Resolved Immunofluorometric Assay of Prostate-Specific Antigen in Serum and Preliminary Clinical Studies".

23552
PATENT TRADEMARK OFFICE

EXAMINER DATE CONSIDERED